

434-1300 PCT/PTO 27 OCT 2000 BOX 566

FORM PTO-1390 (Modified)  
(REV. 11-98)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371

33377-00

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR

09/674368

PRIORITY DATE CLAIMED

INTERNATIONAL APPLICATION NO.

PCT/US99/09486

INTERNATIONAL FILING DATE

April 29, 1999

TITLE OF INVENTION

VACCINES CONTAINING RECOMBINANT PILIN AGAINST NEISSERIA GONORRHOEAE OR NEISSERIA  
MENINGITIDIS

APPLICANT(S) FOR DO/EO/US

METCALF, Thomas N. III, ZAGURSKY, Robert J. and OOI, Peggy

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
  - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ has been transmitted by the International Bureau.
  - c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ A copy of the International Search Report (PCT/ISA/210).
8. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ have been transmitted by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
9. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
10. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 13 to 20 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☒ Certificate of Mailing by Express Mail
20. ☒ Other items or information: ←

Declaration of Alan M. Gordon re:  
deposits  
Sequence Listing Diskette & Rule 1.821(f)  
Statement  
Assignment and Assignment Recordal

11/01/2000 LLANDIGRA 00000011 011300 09674368 CERTIFICATION UNDER 37 C.F.R.. 1.10

04 FEB 2001

40.00 CH

I hereby certify that this paper and the documents referred to as enclosed therein are being deposited with the United States Postal Service on the date written below in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EL704979635US addressed to the Commissioner for Patents, Box Patent Application, Washington, D.C. 20231.

10/27/00

Date

Alan M. Gordon

Name

The PTO did not receive the following  
listed item(s) NO

ASSIGNMENT  
DOCUMENT

|  |  |  |  |   |  |
|--|--|--|--|---|--|
| U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.53(a))<br><b>09/674 368</b> |  | INTERNATIONAL APPLICATION NO.<br><b>PCT/US99/09486</b> |  | ATTORNEY'S DOCKET NUMBER<br><b>33377-00</b> |  |
|--|--|--|--|---|--|

21. The following fees are submitted:

**BASIC NATIONAL FEE ( 37 CFR 1.492 (a)(1) - (5) ) :**

|  |                 |
|--|-----------------|
| <input type="checkbox"/> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO ..... | <b>\$970.00</b> |
| <input checked="" type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO .....  | <b>\$840.00</b> |
| <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO .....  | <b>\$690.00</b> |
| <input type="checkbox"/> International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4) .....   | <b>\$670.00</b> |
| <input type="checkbox"/> International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) .....   | <b>\$96.00</b>  |

**ENTER APPROPRIATE BASIC FEE AMOUNT =**

|   |                 |
|---|-----------------|
| <b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b> | <b>\$840.00</b> |
|---|-----------------|

Surcharge of **\$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).

|  |                     |                     |             |                              |
|--|---------------------|---------------------|-------------|------------------------------|
| <b>CLAIMS</b>  | <b>NUMBER FILED</b> | <b>NUMBER EXTRA</b> | <b>RATE</b> |                              |
| Total claims   | 42 - 20 =           | 22                  | x \$18.00   | <b>\$396.00</b>              |
| Independent claims   | 10 - 3 =            | 7                   | x \$78.00   | <b>\$546.00</b>              |
| Multiple Dependent Claims (check if applicable) <input type="checkbox"/>   |                     |                     |             | <b>\$0.00</b>                |
| <b>TOTAL OF ABOVE CALCULATIONS =</b>   |                     |                     |             | <b>\$1,782.00</b>            |
| Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28) (check if applicable). <input type="checkbox"/>                   |                     |                     |             | <b>\$0.00</b>                |
| <b>SUBTOTAL =</b>  |                     |                     |             | <b>\$1,782.00</b>            |
| Processing fee of <b>\$130.00</b> for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492 (f)). |                     |                     |             | <b>\$0.00</b>                |
| <b>TOTAL NATIONAL FEE =</b>  |                     |                     |             | <b>\$1,782.00</b>            |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable). <input type="checkbox"/>               |                     |                     |             | <b>\$40.00</b>               |
| <b>TOTAL FEES ENCLOSED =</b>   |                     |                     |             | <b>\$1,822.00</b>            |
|  |                     |                     |             | Amount to be:<br>refunded \$ |
|  |                     |                     |             | charged \$                   |

☐ A check in the amount of \_\_\_\_\_ to cover the above fees is enclosed.

☒ Please charge my Deposit Account No. **01-1300** in the amount of \_\_\_\_\_ to cover the above fees.  
A duplicate copy of this sheet is enclosed.

☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. **01-1300** A duplicate copy of this sheet is enclosed.

**NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.**

SEND ALL CORRESPONDENCE TO:

Alan M. Gordon  
Patent Law Department 2B  
American Home Products Corporation  
One Campus Drive  
Parsippany, NJ 07054  
Phone (973) 683-2157

*Alan M. Gordon*

SIGNATURE

Alan M. Gordon

NAME

30,637

REGISTRATION NUMBER

10/27/00

DATE

33,377-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Thomas N. Metcalf III et al.  
Serial No. : To be Assigned (entry into U.S. National  
Stage from PCT/US99/09486)  
Filed : April 29, 1999  
For: : Vaccines Containing Recombinant Pilin  
Against *Neisseria gonorrhoeae* or *Neisseria*  
*meningitidis*  
Examiner : To be Assigned  
Group Art Unit : To be Assigned

BOX PATENT APPLICATION  
Hon. Commissioner for Patents  
Washington, D.C. 20231

DECLARATION OF ALAN M. GORDON

Sir:

I, ALAN M. GORDON, hereby declare and state:

1. I am the attorney of record in the above-  
captioned application in which I represent the inventors.

-----  
CERTIFICATION UNDER 37 C.F.R. 1.10

I hereby certify that this paper and the documents referred to as  
enclosed therein are being deposited with the United States Postal Service on  
the date written below in an envelope as "Express Mail Post Office to Addressee"  
Mailing Label Number EL704979635 addressed to the Assistant Commissioner for  
Patents, Box Patent Application, Washington, D.C. 20231.

10/27/00

Date



Alan M. Gordon

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2. Attached to this Declaration is what I am informed and I believe is a true copy of a Receipt dated February 6, 1998 of a deposit of biological material made by Applicants, which is relevant to the above-captioned application, namely samples of *Escherichia coli* strain K12, TOP10F', harboring plasmid PBCC1166, said deposit having been made on January 27, 1998, with the American Type Culture Collection (ATCC), 12301 Parklawn Drive, Rockville, MD 20852. The deposit was tested and found to be viable on January 30, 1998, and was accorded accession number ATCC 98637 by the ATCC.

3. Also attached to this Declaration is what I am informed and I believe is a true copy of a Receipt dated April 22, 1999 of a deposit of biological material made by Applicants, which is relevant to the above-captioned application, namely samples of *Escherichia coli* strain K12, TOP10F', harboring plasmid pPX8017, PBCC8017, said deposit having been made on April 16, 1999, with the ATCC, 10801 University Blvd., Manassas, VA 20110-2209 (the ATCC moved its location between the making of the first and second deposits). The deposit was tested and found to be viable on April 22, 1999, and was accorded accession number ATCC 207199 by the ATCC.

4. The ATCC is an International Depository Authority under the Budapest Treaty. The deposits ATCC 98637 and 207199 have thus been accepted by an International Depository Authority under the provisions of the Budapest Treaty. In accordance with the terms of the Budapest Treaty, all restrictions upon the availability to the public of the two deposited materials will be irrevocably removed upon the granting of a patent on this application and the deposits will be replaced if viable samples cannot be dispensed by the depository. The deposited materials will be maintained for a period of at least 30 years after the date of deposit, or five years after the most recent request for a sample, whichever is longer.

5. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

10/27/00  
Date

Alan M. Gordon  
ALAN M. GORDON

382 85 1180  
**ATCC**

RECEIVED

APR 27 1999

ALAN M. GORDON

10801 University Blvd • Manassas, VA 20110-2209 • Telephone: 703-365-2700 • FAX: 703-

**BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF  
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE**

**INTERNATIONAL FORM**

**RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3  
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2**

**To: (Name and Address of Depositor or Attorney)**

Wyeth Lederle Vaccines  
Attn: Robert Zagursky, Ph.D.  
211 Bailey Road  
West Henrietta, NY 14564

**Deposited on Behalf of:** American Cyanamid Company, subsidiary of American Home Products Corporation

**Identification Reference by Depositor:**

**ATCC Designation**

*Escherichia coli* K12, TOP10F', harboring plasmid pPX8017, PBCC8017 207199

The deposit was accompanied by: ☐ a scientific description ☒ a proposed taxonomic description indicated above.

The deposit was received April 16, 1999 by this International Depository Authority and has been accepted.

**AT YOUR REQUEST:** ☒ We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

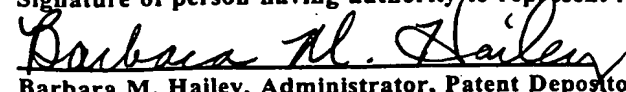
If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested April 22, 1999. On that date, the culture was viable.

**International Depository Authority:** American Type Culture Collection, Manassas, VA 20110-2209 USA.

**Signature of person having authority to represent ATCC:**

  
Barbara M. Hailey, Administrator, Patent Depository

**Date:** April 22, 1999

cc: Alan M. Gordon (Ref. 33,377 PCT)